FEB 18 2000

RÜSCH.
INTERNATIONAL
Group Regulatory Affairs
A Subsidiary of Teleflex Incorporated (USA)

Tall Pines Park
Jaffrey, NH 03452
(603) 532-7706
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K000070

510(k) Summary

1. Submitter Name, Address, and Date of Submission.

Karenann J. Brozowski
Group Regulatory Affairs Associate
Teleflex Inc
Tall Pines Park
Jaffrey, New Hampshire 03452

Telephone: (603) 532-7706
Facsimile: (603) 532-8211
E-Mail: 73451.1040@compuserve.com
Contact: Same as above

2. Name of the Device, Common, Proprietary (if Known), and Classification.

Classification Name: Catheter, Urological

Common Name: Urological Catheter

Proprietary Name: Rüsch FloCath – Uncoated or coated, Sterile

Classification: Class II medical device, 78 KOD, 21CFR 876.5130.

3. Identification of the legally marketed device to which the submitter claims equivalence.

The Rüsch FloCath Catheter is substantially equivalent in materials, design and use to MMG Healthcare (MMGEasyCath™), Conveen (Intermittent Catheters) and Mentor (Self-Cath®).

4. Description of the Device.

The Rüsch FloCath Catheter consists of a tubular PVC shaft with attached drainage funnel. The catheter is designed with either Nelaton, Olive or Tiemann tip. There are two drainage eyes in various configurations (straight through, staggered, vertical oriented). This device shaft may be uncoated or Hydrogel / Hydrophilic coated. The coating has been tested for both its safety and function.

5. Intended Use of the Device.

Rüsch FloCath Catheter is a flexible tubular device that is inserted through the urethra and is used to pass fluids to or from urinary tracts.

6. Summary of Technological Characteristics.

The device is equivalent in design and intended use with MMG Healthcare (MMGEasyCath™), Conveen (Intermittent Catheters) and Mentor (Self-Cath®). The products are tubular PVC shafts with attached drainage funnel as connecting device, with or without Hydrogel / Hydrophilic coating.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Karenann J. Brozowski
Group Regulatory Affairs Director
Rüsch International
Tall Pines Park
Jaffrey, NH 03452

Re: K000070
Rüsch FloCath – Uncoated or Coated
Urological Catheter
Dated: January 10, 2000
Received: January 10, 2000
Regulatory Class: II
21 CFR §876.5130/Procode: 78 KOD

Dear Ms. Brozowski:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K 000070

Device Name: FloCath Catheter

Indications for Use:

FloCath Catheter is a tubular device that is inserted through the urethra and is used to pass fluids to or from urinary tracts.

PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (Per 21 CFR 801.109)

Over-The-Counter Use _____

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K000070